Fluoroscopic Radiation Exposure in Spine Surgery

Robert E. Isaacs, MD
Director of Spine Surgery
Associate Professor
Division of Neurosurgery
Duke University

 Patent Pending LessRay

Disclosures

- Consultant
  - Baxano
  - Nuvasive
  - Vertera
- Stock Holder
  - SafeWire
  - VilaSpine
  - SafeRay Spine
  - Vertera
  - Providence
- Scientific Advisory Board
  - Providence
- Travel Reimbursement
  - Vertera
- ACSR
- Research Support
  - Nuvasive
- Royalties
  - Nuvasive

 Patent Pending LessRay

The Problem

Ionizing radiation exposure during interventional medical procedures using fluoroscopy is a potential health threat to everyone near the x-ray source

 Patented / Patent Pending LessRay

Special Review

Radiology

Shinji Yoshinaga, PhD
Kiyohiko Mabuchi, MD, DrPH
Alice J. Sigurdson, PhD
Michele Morin Doody, MS
Elaine Ron, PhD

Cancer Risks among Radiologists and Radiologic Technologists: Review of Epidemiologic Studies[1]

SHORT REPORT

Increased cancer risk among surgeons in an orthopaedic hospital

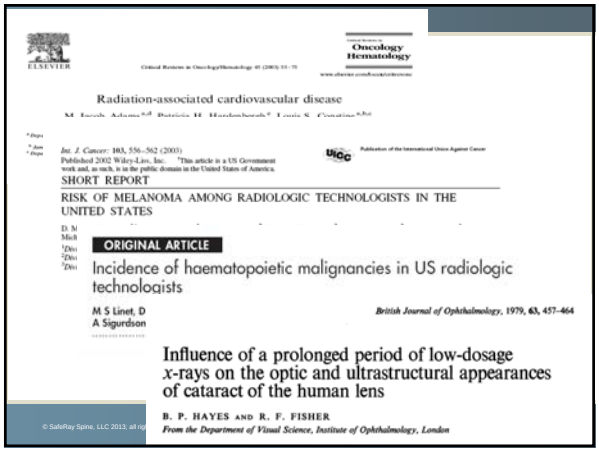
Giuse and B

J Womens Health (Larchmt). 2012 Jun;21(6):683-9. doi: 10.1089/jwh.2011.3342. Epub 2012 Mar 20.

Increased breast cancer prevalence among female orthopedic surgeons.

Chou LB, Chandran S, Harris AH, Tung J, Butler LM.

Department of Orthopaedic Surgery, Stanford University, Stanford, CA 94063, USA. lchou@stanford.edu



ELSEVIER

Oncology Hematology

Radiation-associated cardiovascular disease

Int. J. Cancer: 103, 556–562 (2003)
Published 2002 Wiley-Liss, Inc. This article is a US Government work and, as such, is in the public domain in the United States of America.

UICC Publication of the International Union Against Cancer

SHORT REPORT

RISK OF MELANOMA AMONG RADIOLOGIC TECHNOLOGISTS IN THE UNITED STATES

ORIGINAL ARTICLE

Incidence of haematopoietic malignancies in US radiologic technologists

M S Linet, D
A Sigurdson

British Journal of Ophthalmology, 1979, **63**, 457-464

Influence of a prolonged period of low-dosage *x*-rays on the optic and ultrastructural appearances of cataract of the human lens

B. P. HAYES AND R. F. FISHER

From the Department of Visual Science, Institute of Ophthalmology, London

Deterministic risks (e.g., cataract, osteonecrosis)

Radiation Induced Cataract

Threshold < 500 mGy

Long-term stochastic risks (e.g., cancer)

Patented / Patent Pending

LessRay

But, What About Spine Surgery?

Radiation is Bad…

ELSEVIER THE SPINE JOURNAL

Clinical Study

Management decisions for adolescent idiopathic scoliosis significantly affect patient radiation exposure

Steven M. Presciutti, MD[a,*], Teja Karukanda, BS[a], Mark Lee, MD[b]

"extent of radiation exposure in patients with AIS may elevate the lifetime risk of solid cancers to between 1.4% and 2.4%."

"78% of the annual radiation exposure for operative patients occurs intraoperatively"

 Published by The Spine Journal 14 (2014) 198

J Neurosurg Spine 9:570–573, 2008

Surgeon and patient radiation exposure in minimally invasive transforaminal lumbar interbody fusion

Clinical article

Rajesh K. Bindal, M.D.,[1,2] Sharon Glaze, M.S.,[2,3] Meghann Ognoskie, R.T.,[1] Van Tunner, P.A.,[1] Robert Malone, M.D.,[1] and Subrata Ghosh, M.D.[1,2]

- Prospective study measuring surgeon radiation exposure in MIS TLIF,
  - mean fluoroscopy time of 1.69 minutes per case
  - mean radiation exposure to the surgeon's torso (under a lead apron) of 27 mrem per case.
- Average to patient was 138 mGy

HEALTH RISKS FROM EXPOSURE TO LOW LEVELS OF IONIZING RADIATION
Committee to Assess Health Risks from Exposure to Low Levels of Ionizing Radiation - NATIONAL RESEARCH COUNCIL *OF THE NATIONAL ACADEMIES*

TABLE 12D-1 Lifetime Attributable Risk of Cancer Incidence[a]

	Age at Exposure (years)									
Cancer Site	0	10	15	20	30	40				80
Males										
Stomach	76	65	55	46	40	28	27			7
Colon	285	285	241	204	173	125	122			30
Liver	61	50	43	36	30	22	21			3
Lung	314	268	216	180	149	105	104			34
Prostate	93	80	67	57	48	35	35			5
Bladder	209	177	150	127	108	79	79			23
Other	377	672	568	394	312	195	172			23
Thyroid	113	76	64	33	21	4	3			0.0
All solid	2243	1967	1325	1076	881	615	564			126
Leukemia	237	174	120	96	96	84	84			48
All cancers	2563	2185	1445	1172	977	686	648	591	489	343	174
Females										
Stomach	101	85	72	61	52	36	35			11
Colon	250	187	158	134	114	82	79			23
Liver	20	23	20	16	14	10	10			2
Lung	733	595	504	426	366	242	240			77
Breast	1171	1000	848	712	594	253	141			4
Uterus	50	42	36	30	26	18	16			2
Ovary	104	87	73	60	50	34	31	25	18	11	5
Bladder	212	180	152	129	109	79	78	74	64	47	24
Other	1339	719	523	409	323	207	181	148	109	68	30
Thyroid	634	419	275	178	113	41	14	4	1	0.3	0.0
All solid	4592	3265	2525	1988	1575	1002	824	678	529	358	177
Leukemia	185	112	86	76	71	63	62	62	57	51	37
All cancers	4777	3377	2611	2064	1646	1065	886	740	586	409	214

NOTE: Number of cases per 100,000 persons exposed to a single dose of 0.1 Gy

100,000 women aged 30

Single dose of 100 mGy

Over their lifetime

A Single Dose of 100 mGy

Just Over 1% Increased Lifetime Risk of Cancer!!

Compton Scatter

Increased cancer risk among surgeons in an orthopaedic hospital

- One Ortho Hospital in Italy, 1976-2000
- Ortho – 29% risk
- Exposed (not surgeons) – 6%
- Not Exposed – 4%
- Ortho surgeons – 5X increased risk of cancer

- Mastrangelo G, Fedeli U, Fadda E, Giovanazzi A, Scoizzato L, Saia B. Increased cancer risk among surgeons in an orthopaedic hospital. Occup Med (Lond). 2005;55:498-500.

Spine (Phila Pa 1976). 2000 Oct 15;25(20):2637-45.

Radiation exposure to the spine surgeon during fluoroscopically assisted pedicle screw insertion.

Rampersaud YR1, Foley KT, Shen AC, Williams S, Solomito M.

- Spinal surgeons can sustain a 10- to 12-fold increase in radiation exposure as compared with surgeons using fluoroscopy for nonspinal procedures.

But I'm Protected by Lead?

SPINE Volume 31, Number 21, pp 2316–2320
©2006, Lippincott Williams & Wilkins, Inc.

Radiation Exposure During Pedicle Screw Placement in Adolescent Idiopathic Scoliosis: Is Fluoroscopy Safe?

Mashir Ul Haque, BA,† Harry L. Shufflebarger, MD,* Michael O'Brien, MD,* and Angel Macagno, MD*

- Putting in OPEN fluoroscopically assisted pedicle screws gives the surgeon 13.49 mSv of whole body occupational exposure to ionizing radiation during a typical year
- A surgeon beginning his/her career at age 30 years would exceed the lifetime limit for nonclassified workers in less than 10 years.

How Many Of You Know Your Dosimeter Readings?

In fact, how many of us wear a Dosimeter?

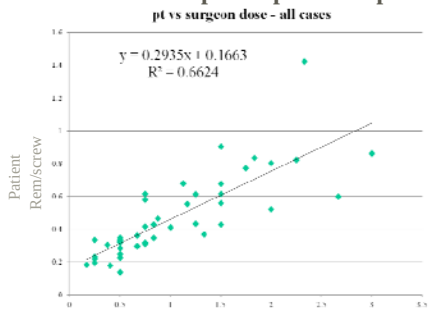
 Patented / Patent Pending LessRay

Results

- 59 MIS fusions were performed over 12 months
- 376 screws were placed
- Average radiation dose to the patient per screw placed was 0.50 Rem
- Average radiation dose to the surgeon per screw placed was 1.01 mRem

Can physician radiation exposure during surgery be predicted based on the patient exposure? Idler, et al SMISS 2014

Surgeon radiation exposure was found to have a linear relationship with patient exposure



Can physician radiation exposure during surgery be predicted based on the patient exposure? Idler, et al SMISS 2014

What About Lead?

SPINE Volume 31, Number 21, pp 2316–2320
©2006, Lippincott Williams & Wilkins, Inc.

Radiation Exposure During Pedicle Screw Placement in Adolescent Idiopathic Scoliosis: Is Fluoroscopy Safe?

Mashir Ul Haque, BA,† Harry L. Shufflebarger, MD,* Michael O'Brien, MD,* and Angel Macagno, [illegible]

- Above the Thyroid Shield - 13.4[illegible] mSv/yr
- Below the Thyroid Shield - [illegible].31 mSv/yr
- So, lead gives a 2/3rds reduction

66%!!

J Neurosurg Spine 9:370–373, 2008

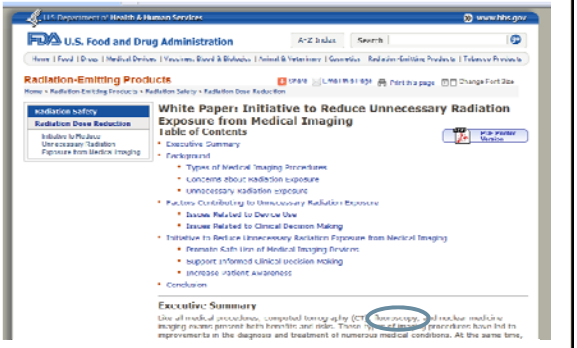
Surgeon and patient radiation exposure in minimally invasive transforaminal lumbar interbody fusion

Clinical article

Rajesh K. Bindal, M.D.,[1] Sharon Glaze, M.S.,[2,3] Meghann Ognoskie, R.T.,[3] Van Tunner, P.A.,[3] Robert Malone, M.D.,[3] and Subrata Ghosh, M.D.[3,5]

- Lead protects what is closer to the x-ray source, but the radiation that gets through is substantial
- At the waist PROTECTED by a lead apron was 27 mRem
- At the UNPROTECTED thyroid level was 32 mRem

84%



U.S. Food and Drug Administration

Radiation-Emitting Products

Radiation Safety

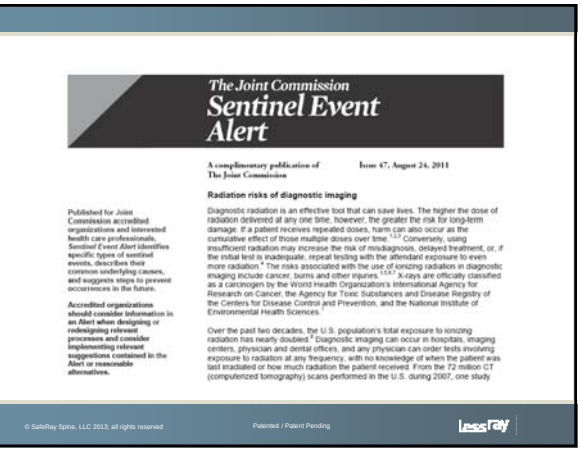
Radiation Dose Reduction

White Paper: Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging

Table of Contents

- Executive Summary
- Background
  - Types of Medical Imaging Procedures
  - Concerns about radiation exposure
  - Unnecessary radiation exposure
- Factors Contributing to Unnecessary Radiation Exposure
  - Issues Related to Device Use
  - Issues Related to Clinical Decision Making
- Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging
  - Promote Collection of Medical Imaging Features
  - Support informed clinical decision making
  - Increase patient awareness
- Conclusion

Executive Summary



The Joint Commission

Sentinel Event Alert

A complimentary publication of The Joint Commission

Issue 47, August 24, 2011

Radiation risks of diagnostic imaging

Published for Joint Commission accredited organizations and interested health care professionals, Sentinel Event Alert identifies specific types of sentinel events, describes their common underlying causes, and suggests steps to prevent occurrences in the future.

Accredited organizations should consider information in an Alert when designing or redesigning relevant processes and consider implementing relevant suggestions contained in the Alert or reasonable alternatives.

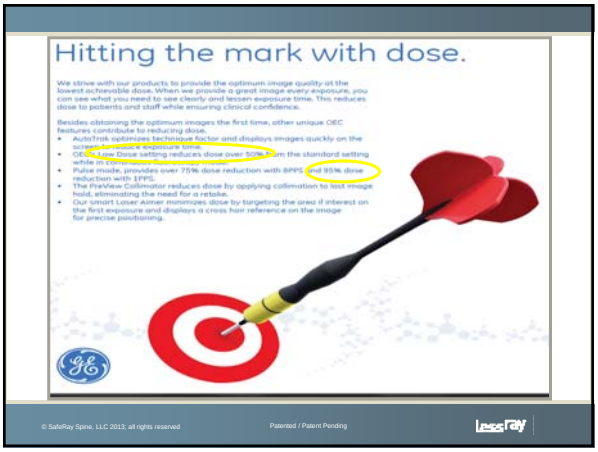
Diagnostic radiation is an effective tool that can save lives. The higher the dose of radiation delivered at any one time, however, the greater the risk for long-term damage. If a patient receives repeated doses, harm can also occur as the cumulative effect of those multiple doses over time.[1,2,3] Conversely, using insufficient radiation may increase the risk of misdiagnosis, delayed treatment, or, if the initial test is inadequate, repeat testing with the attendant exposure to even more radiation.[4] The risks associated with the use of ionizing radiation in diagnostic imaging include cancer, burns and other injuries.[5,6,7] X-rays are officially classified as a carcinogen by the World Health Organization's International Agency for Research on Cancer, the Agency for Toxic Substances and Disease Registry of the Centers for Disease Control and Prevention, and the National Institute of Environmental Health Sciences.

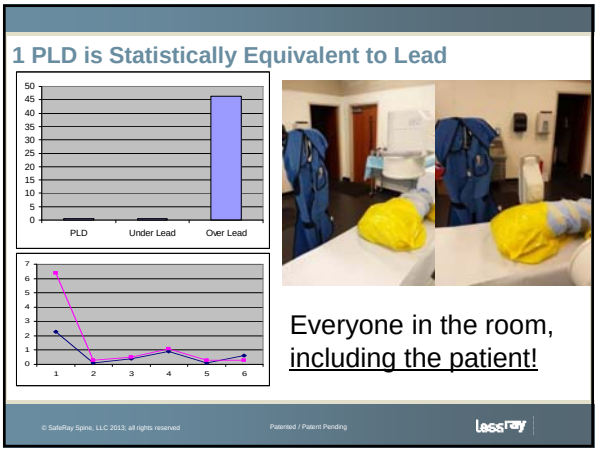
Over the past two decades, the U.S. population's total exposure to ionizing radiation has nearly doubled.[8] Diagnostic imaging can occur in hospitals, imaging centers, physician and dental offices, and any physician can order tests involving exposure to radiation at any frequency, with no knowledge of when the patient was last irradiated or how much radiation the patient received. From the 72 million CT (computerized tomography) scans performed in the U.S. during 2007, one study

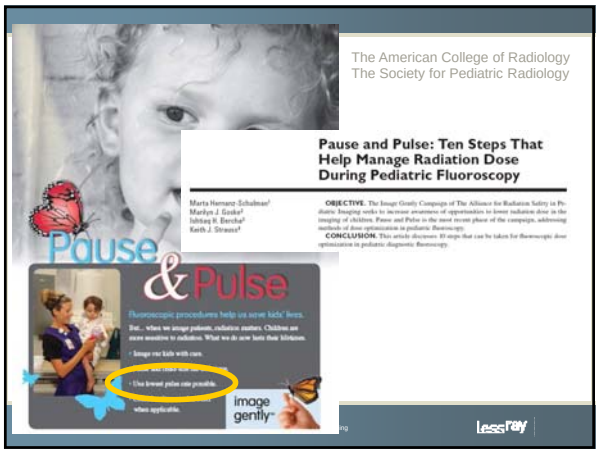
The Solution

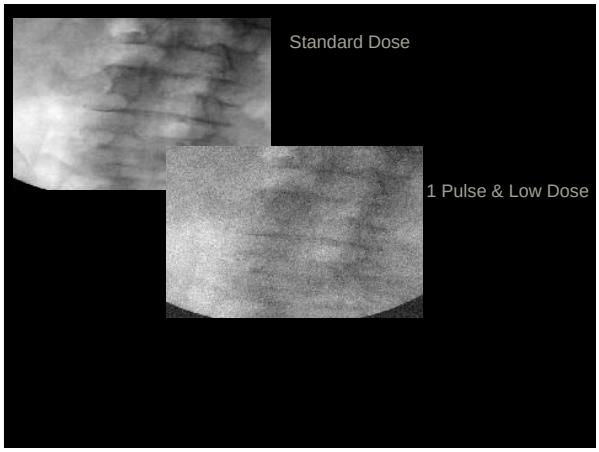
Use Pulse and/or Low Dose Imaging
to achieve ALARA – radiation dosing
"As Low As Reasonably Achievable"

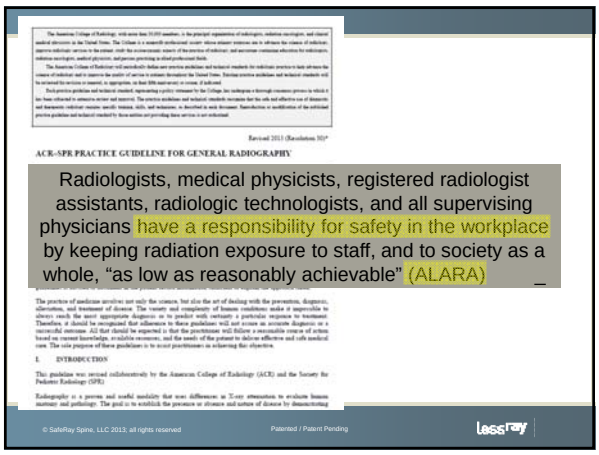

© SafeRay Spine, LLC 2013; all rights reserved
Patented / Patent Pending
LessRay


Hitting the mark with dose.
We strive with our products to provide the optimum image quality at the lowest achievable dose. When we provide a great image every exposure, you can see what you need to see clearly and lessen exposure time. This reduces dose to patients and staff while ensuring clinical confidence.
Besides obtaining the optimum images the first time, other unique OEC features contribute to reducing dose.
AutoTrak optimizes technique factor and displays images quickly on the screen to reduce exposure time.
OEC's Low Dose setting reduces dose over 50% from the standard setting while in cine mode. Image quality remains excellent.
Pulse mode, provides over 75% dose reduction with 8PPS and 95% dose reduction with 1PPS.
The PreView Collimator reduces dose by applying collimation to last image hold, eliminating the need for a retake.
Our smart Laser Aimer minimizes dose by targeting the area of interest on the first exposure and displays a cross hair reference on the image for precise positioning.
© SafeRay Spine, LLC 2013; all rights reserved
Patented / Patent Pending
LessRay


1 PLD is Statistically Equivalent to Lead
50
45
40
35
30
25
20
15
10
5
0
PLD
Under Lead
Over Lead
7
6
5
4
3
2
1
0
1
2
3
4
5
6
Everyone in the room,
including the patient!
© SafeRay Spine, LLC 2013; all rights reserved
Patented / Patent Pending
LessRay


The American College of Radiology
The Society for Pediatric Radiology
Pause and Pulse: Ten Steps That Help Manage Radiation Dose During Pediatric Fluoroscopy
Pause & Pulse
Fluoroscopic procedures help us save kids' lives.
image gently
LessRay


Standard Dose
1 Pulse & Low Dose


ACR-SPR PRACTICE GUIDELINE FOR GENERAL RADIOGRAPHY
Radiologists, medical physicists, registered radiologist assistants, radiologic technologists, and all supervising physicians have a responsibility for safety in the workplace by keeping radiation exposure to staff, and to society as a whole, "as low as reasonably achievable" (ALARA)
I. INTRODUCTION
© SafeRay Spine, LLC 2013; all rights reserved
Patented / Patent Pending
LessRay

Revised 2013 (Resolution 35)*

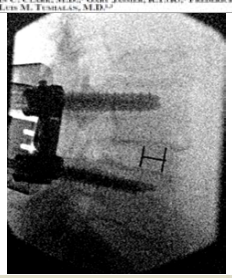
ACR-SPR PRACTICE GUIDELINE FOR GENERAL RADIOGRAPHY

Radiologists, medical physicists, registered radiologist assistants, radiologic technologists, and all supervising physicians have a responsibility for safety in the workplace by keeping radiation exposure to staff, and to society as a whole, “as low as reasonably achievable” (ALARA) and to assure that radiation doses to individual patients are appropriate, taking into account the possible risk from radiation exposure and **the diagnostic image quality necessary to achieve the clinical objective**.

Neurosurg Focus 35 (2):E8, 2013
©AANS, 2013

Minimally invasive transforaminal lumbar interbody fusions and fluoroscopy: a low-dose protocol to minimize ionizing radiation

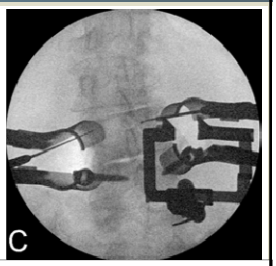
Justin C. Clark, M.D.,[1] Gaby Jasmer, R.T.(R),[2] Frederick F. Marciano, M.D., Ph.D.,[1,2] and Luis M. Tumialan, M.D.[1,2]



 Patented / Patent Pending LaserRay

“Detail of the pedicle is lost with the low-dose pulsed fluoroscopy”

“For finer detail, specifically when determining the medial boundary of the pedicle on an AP view, digital spot is preferable.”



Neurosurg Focus 35 (2):E8, 2013
©AANS, 2013

Minimally invasive transforaminal lumbar interbody fusions and fluoroscopy: a low-dose protocol to minimize ionizing radiation

Justin C. Clark, M.D.,[1] Gaby Jasmer, R.T.(R),[2] Frederick F. Marciano, M.D., Ph.D.,[1,2] and Luis M. Tumialan, M.D.[1,2]

Confidential

lessray

 Patent Pending

What Is LessRay?

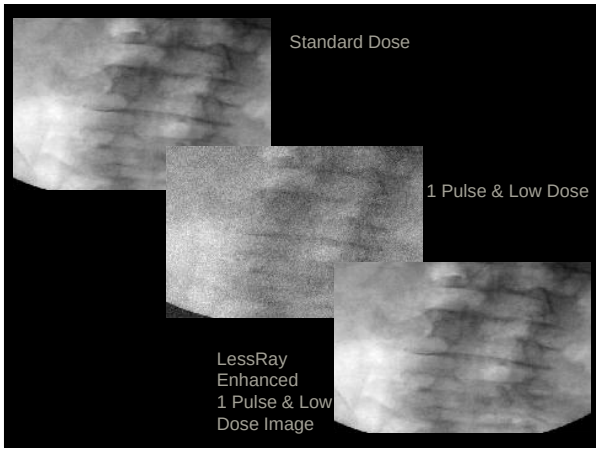
Pulse and Low Dose degrade image quality - LessRay can improve it to close to full dose imaging

 Patented / Patent Pending

Components of LessRay

 Patented / Patent Pending

Set Up



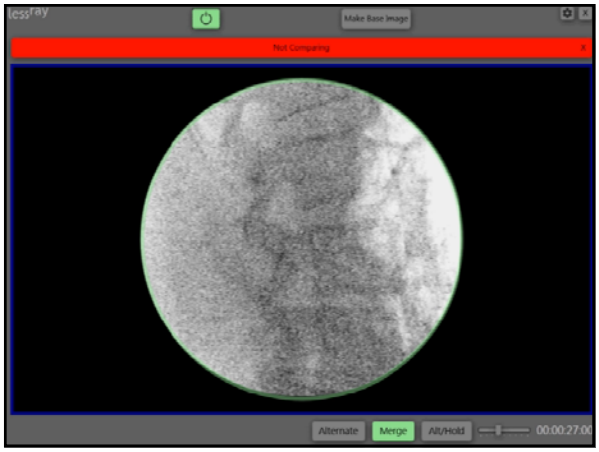
LessRay:

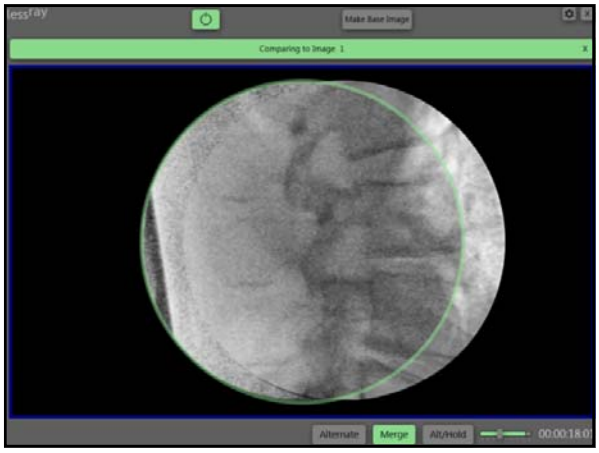
In clinical practice, the amount of image quality improvement achieved when a Pulsed and/or Low Dose image is processed with LessRay is dependent on the clinical task, patient size, anatomical location, and clinical practice. The dose should be set at a level to which the physician is able to achieve the adequate image quality needed for the particular clinical task. A consultation with a radiologist and a physicist may aid in determining the appropriate dose settings.

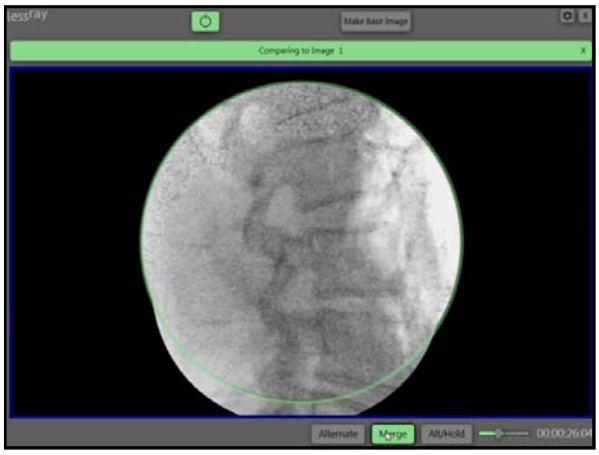
The Technology

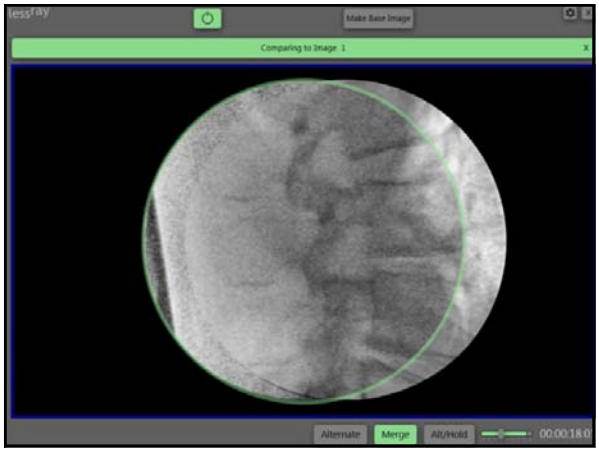
Patent Pending

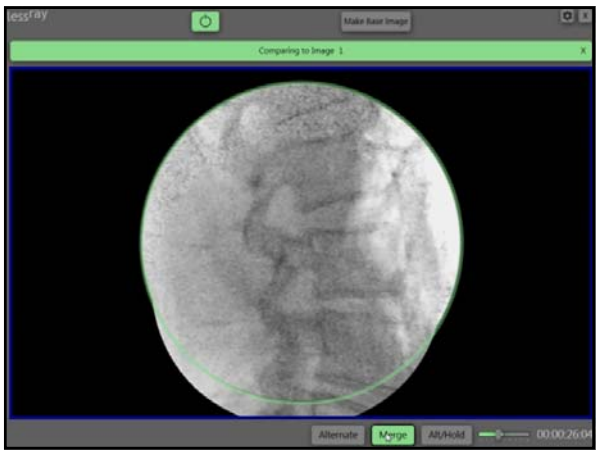
lessRay

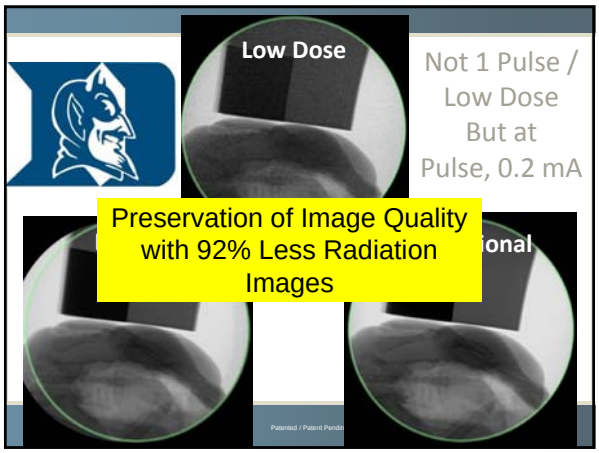


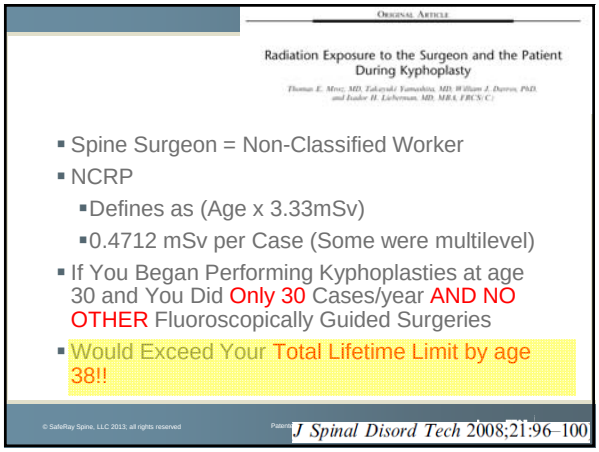


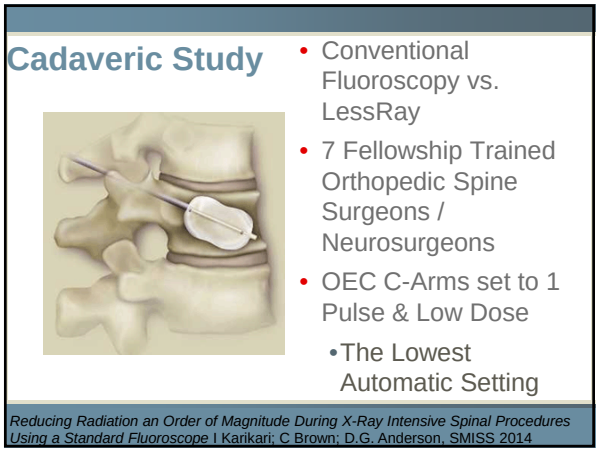

Make Base Image
Comparing to Image 1
Alternate
Merge
Alt/Hold
00:00:26:04

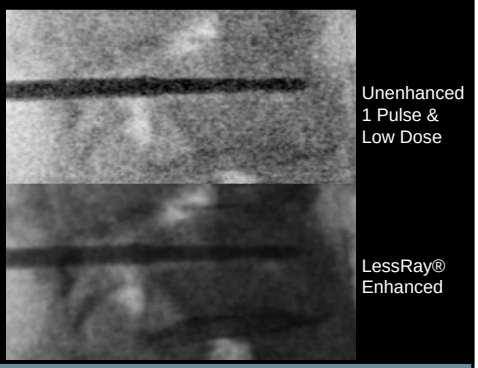

Make Base Image
Comparing to Image 1
Alternate
Merge
Alt/Hold
00:00:18:0


Make Base Image
Comparing to Image 1
Alternate
Merge
Alt/Hold
00:00:26:04

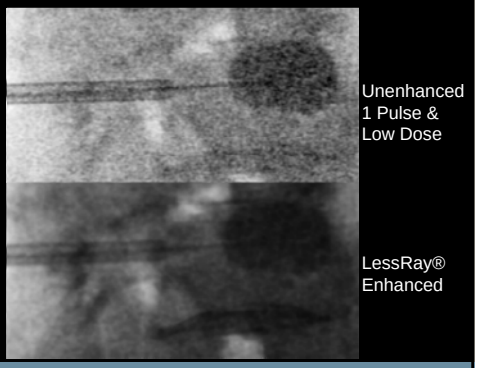

Low Dose
Not 1 Pulse / Low Dose But at Pulse, 0.2 mA
Preservation of Image Quality with 92% Less Radiation Images
ional
Patented / Patent Pendin


Original Article
Radiation Exposure to the Surgeon and the Patient During Kyphoplasty
Thomas E. Mroz, MD, Takayuki Yamashita, MD, William J. Dupree, PhD, and Isador H. Lieberman, MD, MBA, FRCS(C)
Spine Surgeon = Non-Classified Worker
NCRP
Defines as (Age x 3.33mSv)
0.4712 mSv per Case (Some were multilevel)
If You Began Performing Kyphoplasties at age 30 and You Did Only 30 Cases/year AND NO OTHER Fluoroscopically Guided Surgeries
Would Exceed Your Total Lifetime Limit by age 38!!
© SafeRay Spine, LLC 2013; all rights reserved
J Spinal Disord Tech 2008;21:96–100


Cadaveric Study
Conventional Fluoroscopy vs. LessRay
7 Fellowship Trained Orthopedic Spine Surgeons / Neurosurgeons
OEC C-Arms set to 1 Pulse & Low Dose
The Lowest Automatic Setting
Reducing Radiation an Order of Magnitude During X-Ray Intensive Spinal Procedures Using a Standard Fluoroscope I Karikari; C Brown; D.G. Anderson, SMISS 2014



Reducing Radiation an Order of Magnitude During X-Ray Intensive Spinal Procedures Using a Standard Fluoroscope I Karikari; C Brown; D.G. Anderson, SMISS 2014



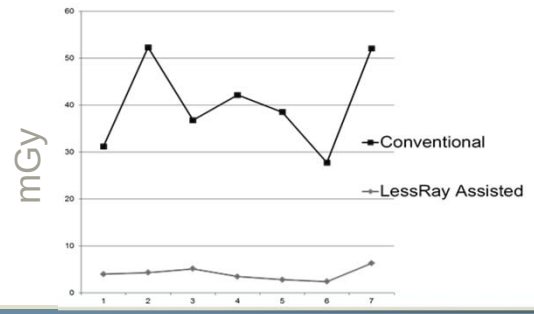
Reducing Radiation an Order of Magnitude During X-Ray Intensive Spinal Procedures Using a Standard Fluoroscope I Karikari; C Brown; D.G. Anderson, SMISS 2014

Results

- In no case did any of the physicians abandon the LessRay enhanced images.
- The average duration of fluoroscopy time for the entire procedure was 65.6s vs. 11.0s (Conventional vs LessRay-Assisted, $p<0.001$).
- Statistically similar number of images with both methods prior to cement injection (24 vs. 21, $p=0.30$)
- The pulsed/low dosed procedures achieved an overall 88.8% radiation reduction over conventional imaging (36.1mGy vs. 4mGy, $p< 0.001$).

Reducing Radiation an Order of Magnitude During X-Ray Intensive Spinal Procedures Using a Standard Fluoroscope I Karikari; C Brown; D.G. Anderson, SMISS 2014

Radiation Per Procedure



Reducing Radiation an Order of Magnitude During X-Ray Intensive Spinal Procedures Using a Standard Fluoroscope I Karikari; C Brown; D.G. Anderson, SMISS 2014

Conclusions:

Digitally improvement allows the physician to use the lowest radiation settings on a C-Arm

Significantly reduces the amount of radiation exposure during a radiation intensive medical procedure when compared with conventional fluoroscopy

With the aid of image enhancement software like LessRay®, a fluoroscope can provide high quality images with an order of magnitude less radiation we are currently being subjected to.

Reducing Radiation an Order of Magnitude During X-Ray Intensive Spinal Procedures Using a Standard Fluoroscope I Karikari; C Brown; D.G. Anderson, SMISS 2014

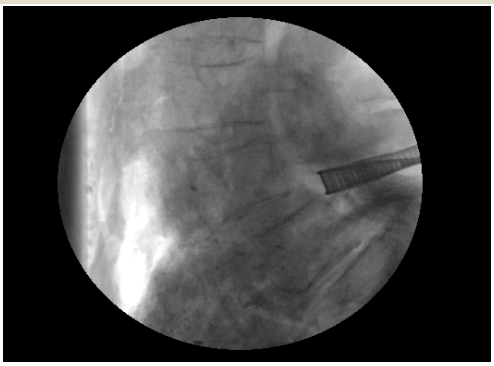
LessRay

Metal Elimination

Patented / Patent Pending

LessRay

Patented / Patent Pending
lessRay



Patented / Patent Pending
lessRay

Conclusions

 Patented / Patent Pending lessray

Lessray:

-Improve Low Radiation Images